K110313

DEC 23 2011

510(k) Summary – Tina-quant HbA1c Gen.2 Assay

Introduction

Roche Diagnostics Corporation hereby submits this 510(k) to provide notification of our intent to market Tina-quant HbA1c Gen.2 assay.

Submitter, name, address, contact

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Date prepared: January 31, 2011

Device name

Proprietary name: Tina-quant Hemoglobin A1c Gen.2 assay

Common name: HbA1c Gen.2

Classification name: Glycosylated Hemoglobin assay

Product code: LCP

Device description

With the Tina-Quant Hemoglobin A1c Gen.2 test system, the anticoagulated whole blood specimen is hemolyzed prior to determination of HbA1c by a turbidimetric inhibition immunoassay (TINIA). Liberated hemoglobin (Hb) in the hemolyzed sample is converted to a derivative having a characteristic absorption spectrum and measured bichromatically. The instrument calculates the % HbA1c from the HbA1c/Hb ratio according to a user selected protocol.

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510(k) Summary – Tina-quant HbA1c Gen. 2 Assay, continued

Intended use	The Tina-Quant Hemoglobin A1c Gen.2 assay is an in vitro diagnostics reagent system intended for quantitative determination of mmol/mol hemoglobin A1c (IFCC) and % hemoglobin A1c (DCCT/NGSP) in hemolysate or whole blood on Roche clinical chemistry analyzers. HbA1c determinations are useful for monitoring of long-term blood glucose control in individuals with diabetes mellitus.
Predicate device	We claim substantial equivalence to the currently marketed device Tina-quant Hemoglobin A1c Gen.2 cleared in K072714.

Substantial equivalence

The following table compares the features of the two Tina-quant HbA1c Gen.2 assays, the predicate device and the candidate device.

Feature	Predicate Device: HbA1c Gen. 2 (K072714)	Candidate Device: HbA1c Gen. 2
Intended Use	**Whole blood application** In vitro test for the quantitative determination of percent hemoglobin A1c [HbA1c (%)] in whole blood on Roche clinical chemistry analyzers **Hemolysate Application**: In vitro test for the Quantitative determination of percent hemoglobin A1c [HbA1c (%)] in hemolysate prepared from whole blood on Roche clinical chemistry analyzers	**Whole blood application** In vitro test for the quantitative determination of mmol/mol hemoglobin A1c (IFCC) and % hemoglobin A1c (DCCT/NGSP) in whole blood on Roche clinical chemistry analyzers **Hemolysate Application** In vitro test for the quantitative determination of mmol/mol hemoglobin A1c (IFCC) and % hemoglobin A1c (DCCT/NGSP) in hemolysate prepared from whole blood on Roche clinical chemistry analyzers
Sample Types	Anticoagulated venous or capillary blood Acceptable anticoagulants for both the hemolysate and whole blood applications include • Li-heparin • K2-EDTA • K3-EDTA • KF/Na_2-EDTA	Anticoagulated venous or capillary blood Acceptable anticoagulants for both the hemolysate and whole blood applications include • Li-Heparin • K2-EDTA • K3-EDTA • KF/Na_2-EDTA Acceptable anticoagulants for the hemolysate application include • Na-Heparin • NaF/K-Oxalate • NaF/Na_2-EDTA

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510(k) Summary – Tina-quant HbA1c Gen. 2 Assay, continued

Substantial equivalence (continued)

Feature	Predicate Device: HbA1c Gen. 2 (K072714)	Candidate Device: HbA1c Gen. 2
Instrument Platform	Integra 400/400 plus Integra 800 and Integra 800 CTS (Closed Tube system)	same
Calibrator	Cfas HbA1c	same
Calibration Frequency	Each lot, every 29 days, and as required following quality control procedures	same
Calibration Mode	Logit/log 5	same
Controls	• HbA1c Control N • HbA1c Control P	• HbA1c Control N • HbA1c Control P • PreciControl HbA1c norm and path (cleared in K103099)
Reagent Stability	**Unopened** 2-8 °C until expiration date **On-board in use** Integra 400/400plus 10-15°C for 28 days Integra 800 8°C for 28 days	same
Measuring Range	**Integra 400/400 plus** Hb: 4 – 35 g/dL HbA1c: 0.3 – 2.6 g/dL* * Based on concentration of the highest standard. This test range is based on a typical calibrator value of 2.6 g/dL. **Integra 800** Hb: 4 – 35 g/dL HbA1c: 0.3 – 3.4 g/dL	same
Reporting Units	% HbA1c NGSP / DCCT	% HbA1c NGSP/DCCT and mmol/mol IFCC
Antibody	Polyclonal anti-HbA1c from sheep blood	same

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510(k) Summary – Tina-quant HbA1c Gen. 2 Assay, continued

Substantial equivalence (continued)

Feature	Predicate Device: HbA1c Gen. 2 (K072714)	Candidate Device: HbA1c Gen. 2
Precision	**Whole blood application** Within-run: 0.8% @ 5.4 % HbA1c 0.9% @ 10.2 % HbA1c Between day: 1.3% @ 5.3 % HbA1c 1.0% @ 10.3 % HbA1c **Hemolysate Application**: Within-run: 1.0% @ 5,5 % HbA1c 0.6% @ 10.6 % HbA1c Between day: 1.0 % @ 5.3 % HbA1c 0.8% @ 10.7 % HbA1c	same Change in nomenclature: "Within-run" is now called "Repeatability" and "Between day is now called "Intermediate precision."
Expected Values	**Protocol 1** 2.9 – 4.2 % HbA1c (acc. to IFCC) **Protocol 2** 4.8 -5.9 % HbA1c (acc. to DCCT/NGSP)	**Protocol 1** 29 – 42 mmol/mol HbA1c (acc. IFCC) **Protocol 2** same
Determination of HbA1c	Turbidimetric immunoinhibition (TINIA). Antigen-antibody complexes are formed and excess Ab aggregate with polyhapten to form insoluble complexes	same
Determination of Hb	Bichromatic photometric determination after conversion to a colored derivate	same
Pretreatment	**Whole blood application** automated on-board sample pretreatment with hemolyzing reagent **Hemolysate Application**: Manual pretreatment with hemolyzing reagent	same

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510(k) Summary – Tina-quant HbA1c Gen. 2 Assay, continued

Substantial equivalence (continued)

Feature	Predicate Device: HbA1c Gen. 2 (K072714)	Candidate Device: HbA1c Gen. 2
Analytical Sensitivity	**LDL** Hb: 0.5 g/dL HbA1c: 0.1 g/dL	**LOB and LOD** Hb: LOB = 0.31 mmol/L (0.50 g/dL) LOD = 0.62 mmol/L (1.0 g/dL) HbA1c: LOB = 0.12 mmol/L (0.19 g/dL) LOD = 0.18 mmol/L (0.29 g/dL)
Analytical Specificity	Hb derivates: Labile HbA1c (pre-HbA1c), acetylated Hb, carbamylated Hb do not affect the assay result Hb variants: Specimens containing high amounts of HbF (> 10 %) may yield lower than expected HbA1c results	same
Endogenous Interferences	**Icterus** no significant interference **Rheumatoid factors** no significant interference up to 750 IU/mL **Glycemia** no significant interference up to 1000 mg/dL **Lipemia** Integra 400/400 plus analyzers: No significant interference up to a triglycerides concentration of 600 mg/dL Integra 800 analyzer: No significant interference up to a triglycerides concentration of 800 mg/dL	same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Roche Diagnostics Corporation
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Indianapolis, Indiana 46250

DEC 23 2011

Re: k110313
Trade Name: Roche Tina Quant HbA1c Gen. 2 Assay
Regulation Number: 21 CFR §864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Codes: LCP
Dated: December 21, 2011
Received: December 22, 2011

Dear Ms. Hollandbeck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K110313

Device Name: Tina-quant HbA1c Gen.2

Indications for Use:

The Tina-Quant Hemoglobin A1c Gen. 2 assay is an in vitro diagnostic reagent system intended for quantitative determination of mmol/mol hemoglobin A1c (IFCC) and % hemoglobin A1c (DCCT/NGSP) in hemolysate or whole blood on Roche clinical chemistry analyzers. HbA1c determinations are useful for monitoring of long-term blood glucose control in individuals with diabetes mellitus.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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